Annex C – Summary of Defects Described in Briefing

Date	AC ¶	Source	Challenged Statement[1]	Defects Described in Briefing for 10(b) Liability[2]
6/13/20	44	Press release	On Saturday, June 13, 2020, AstraZeneca issued a press release announcing an agreement with Europe's Inclusive Vaccines Alliance to supply up to 400 million doses of AZD1222. The press release also highlighted "the start of a Phase II/III UK trial of AZD1222 in about 10,000 adult volunteers" launched by Oxford the previous month.	• Only second sentence challenged; Plaintiffs do not challenge statements about supply agreements (Opp. n.2) • Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 3-7) • Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4) • Inactionable critique of trial design (Mov. 17, 18, 22-24 & nn.15, 22; Reply 6)
7/20/20	47	Press release	. . . ***Late-stage Phase II/III trials are currently underway in the UK, Brazil and South Africa*** and are due to start in the US. Trials will determine how well the vaccine will protect from the COVID-19 disease and measure safety and immune responses ***in different age ranges*** and at various doses.	• Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 3-7) • Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4) • Inactionable critique of trial design (Mov. 17, 18, 22-24 & nn.15, 22; Reply 6) • Safe harbor for FLS (Mov. 26-27; Reply 9-10)
7/30/20	49	Form 6-K	. . . Initial data was reviewed in May 2020 by a Data Safety Monitoring Board and the UK Medicines and Healthcare products Regulatory Agency, ***resulting in the advancement to the COV002 Phase II/III trial in the UK, with over 10,000 participants***.	• Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 6-7) • Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4)

[1] For lengthy block quotes, Plaintiffs concede that only bolded, italicized portions are challenged. Opp. n.9; Reply n.2. This table summary therefore reproduces only highlighted portions from lengthy blocked quotes.

[2] For all challenged statements, Section 10(b) liability is also precluded for failure to plead particularized facts giving rise to a strong inference of scienter, Mov. Point I.B; Reply Point I.B, and failure to plead loss causation, Mov. Point I.C; Reply Point I.C. For all challenged statements, Section 20(a) liability is precluded given no underlying section 10(b) liability. Mov. Point II; Reply n.21.

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			. . . ***COV002 has launched and has recruited almost 9,000 participants in the UK; late-stage development has begun in Brazil and South Africa***.	
7/30/20	50	Form 6-K	AstraZeneca reiterated that ***"[l]ate stage trials are currently underway in the UK, Brazil and South Africa*** and are due to start in the US. These trials will determine how well the vaccine will protect from the COVID-19 disease and measure safety and immune responses ***in different age ranges***, at various doses." AstraZeneca further discussed its vaccine trials, in pertinent part, as follows: ***During the period, AstraZeneca advanced its ongoing response to address COVID-19*** . . . . Initial data was reviewed in May 2020 by a Data Safety Monitoring Board and the UK Medicines and Healthcare products Regulatory Agency, ***resulting in the advancement to the COV002 Phase II/III trial in the UK, with over 10,000 participants***.	• Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 3-7) • Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4) • Inactionable critique of trial design (Mov. 17, 18, 22-24 & nn.15, 22; Reply 6) • Challenge to "advanced its ongoing response" is also inactionable puffery and opinion (Mov. 18-19, 25-26 & nn.16, 24; Reply 7-8), and protected by safe harbor for FLS (Mov. 26-27; Reply 9-10)
7/30/20	51	Conf. call	We're really proud to be at the forefront and highly active in the pursuit of tackling the COVID-19 global health crisis. . . . ***Late-stage trials are currently ongoing in the U.K., in Brazil, in South Africa and are about to start in the United States.***	• Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 6-7) • Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4) • Challenge to "proud" and "highly active" is also inactionable puffery and opinion (Mov. 25-26 & n.24, Reply 7-8)

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7/30/20	52	Conf. call	. . . ***I think we're very pleased that both our data shows that we're getting a good level of neutralizing antibody presentation in the patients that are vaccinated with the 2 doses as well as a good T cell response. The study remains on track. As you know, we've dosed now nearly 12,000 patients around the world, in the U.K., Brazil and South Africa, and we're about to start the Phase III program in the U.S.***	• Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 6-7) • Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4) • Inactionable challenge to clinical data interpretation (Mov. 19-20 & n.17; Reply 4, 7) • Inactionable opinion (Mov. 19-20 & n.17; Reply 7-8) • Ongoing analysis of incoming data is protected by safe harbor for FLS (Mov. 26-27; Reply 9-10) • Challenge to "on track" is also inactionable puffery and opinion (Mov. 18-19, 25-26 & nn.16, 24; Reply 7-8)
7/30/20	53	Conf. call	So the studies that we have running in the U.K., Brazil, South Africa and soon to start in the U.S. will all be 2-dose studies. And the data readouts from either the U.K. study, the Brazilian study or the South African study or a combination of those could be sufficient for regulatory approvals around the world, just to be clear.	• Challenge to "regulatory approvals" is abandoned (Opp. n.23) ("the AC does not criticize . . . [AZN's] expectations regarding any type of approval") • Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 3-6) • Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4)
7/30/20	54	Conf. call	. . . ***So data on different age groups is coming from the Phase I study and from the Phase II part and the Phase III study we're running in the U.K., and we're getting that data in on a weekly basis***. . . .	• Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 3-6) • Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4) • Inactionable critique of trial design (Mov. 17, 18, 22-24 & nn.15, 22; Reply 6) • Safe harbor for FLS (Mov. 26-27; Reply 9-10)
8/14/20	57	Press release	. . . ***Clinical development of AZD1222 is progressing globally with late-stage Phase II/III trials ongoing in the UK and Brazil***. . . .	• Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 6-7)

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				• Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4) • Challenge to "progressing globally" is also inactionable puffery and opinion (Mov. 18-19, 25-26 & nn.16, 24; Reply 7-8), and protected by safe harbor for FLS (Mov. 26-27; Reply 9-10)
8/31/20	60	Press release	At the heart of AstraZeneca's core values is to "follow the science" and ***adhere to the highest scientific and clinical standards***, making the safety and efficacy of the vaccine of paramount importance. ***The Company's submissions for market authorisation will meet the stringent requirements established by regulators everywhere around the world.*** . . . Pascal Soriot, Chief Executive Officer, said: "***In recent weeks we have seen an increasing number of questions around the safety and availability of vaccines to fight this terrible COVID-19 pandemic and I want to reiterate my commitment that we are putting science and the interest of society at the heart of our work. We are moving quickly but without cutting corners, and regulators have clear and stringent efficacy and safety standards for the approval of any new medicine, and that includes this potential COVID-19 vaccine. We will remain true to our values as we continue our efforts to bring this vaccine broadly and equitably to billions of people around world***."	• Laundry list of alleged omissions do not render false (Mov. 21, 22-25 & n.22; Reply 8 & n.10) • Inactionable as too generalized (Mov. 21 & n.19; Reply 8-9) • Challenge to future submissions is protected by safe harbor for FLS (Mov. 26-27; Reply 9-10)
8/31/20	61	Press release	. . . AstraZeneca "is today issuing a commitment to the highest safety standards and to broad and equitable access," reiterating its core values to "'follow the science' and 'put patients first.'"	• Laundry list of alleged omissions do not render false (Mov. 21, 22-25 & n.22; Reply 8 & n.10) • Inactionable as too generalized (Mov. 21 & n.19; Reply 8-9)

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9/8/20	63	Pledge	AstraZeneca and Soriot vowed that the Company's Covid vaccine development would adhere to the highest manufacturing and clinical standards and "uphold the integrity of the scientific process." . . . All nine CEOs signed the following pledge: *We, the undersigned biopharmaceutical companies, want to make clear our on-going commitment to developing and testing potential vaccines for COVID-19 in accordance with high ethical standards and sound scientific principles.* . . . *Following guidance from expert regulatory authorities such as FDA regarding the development of COVID-19 vaccines, consistent with existing standards and practices, and in the interest of public health, we pledge to:* • *Always make the safety and well-being of vaccinated individuals our top priority.* • *Continue to adhere to high scientific and ethical standards regarding the conduct of clinical trials and the rigor of manufacturing processes.* • *Only submit for approval or emergency use authorization after demonstrating safety and efficacy through a Phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as FDA.* • *Work to ensure a sufficient supply and range of vaccine options, including those suitable for global access. . . .*	• Laundry list of alleged omissions do not render false (Mov. 21, 22-25 & n.22; Reply 8 & nn.10, 11) • Inactionable as too generalized (Mov. 21 & n.19; Reply 8-9) • Safe harbor for FLS (Mov. 26-27; Reply 9-10)
9/8/20	67	Conf. call	"[n]o comment was provided [by Soriot] on when or if trial enrolment will resume" following the two vaccine-trial pauses due to subjects experiencing medical conditions, "rather ***Mr Soriot just expressed his confidence in the design of the***	• Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 7)

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			trials, safety protocols and DSM [data safety monitoring]."	• Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4) • Inactionable critique of trial design (Mov. 17, 18, 22-24 & nn.15, 22; Reply 6) • Inactionable puffery and opinion (Mov. 25-26 & n.24; Reply 7) • Safe harbor for FLS (Mov. 26-27; Reply 9-10)
10/26/20	70	Email from AZ spokes-person	"It is encouraging to see immunogenicity responses were similar between older and younger adults and that reactogenicity was lower in older adults, where the COVID-19 disease severity is higher."	• No Individual Defendant can be liable as "maker," as expressly attributed to someone else and not group-published (Reply 15) • Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 4-6) • Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4) • Inactionable critique of trial design (Mov. 17, 18, 22-24 & nn.15, 22; Reply 6) • Inactionable challenge to clinical data interpretation (Mov. 19-20 & n.17; Reply 4, 7) • Inactionable opinion (Mov. 19-20; Reply 7-8) • Safe harbor for FLS (Mov. 26-27; Reply 9-10)
11/5/20	72	Form 6-K	. . . Data on immunogenicity and safety of in [sic] older adults was presented at IDWeek showing AZD1222 has an acceptable tolerability profile and is immunogenic in adults above 18 years of age, ***including older adults***. Stronger immune responses were shown after a second dose given one month apart, ***across all adult age ranges. Local and systemic reactions were lower in older adults than younger adults (<55 years) and reactions were lessened after the second dose.***	• Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 4-6) • Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4) • Inactionable critique of trial design (Mov. 17, 18, 22-24 & nn.15, 22; Reply 6) • Inactionable challenge to clinical data interpretation (Mov. 19-20 & n.17; Reply 4, 7) • Inactionable opinion (Mov. 20; Reply 7-8)

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				• Ongoing analysis of incoming data is protected by safe harbor for FLS (Mov. 26-27; Reply 9-10)
11/5/20	73	Form 6-K	Mr. Soriot "signed a vaccines pledge in collaboration with nine biopharmaceutical CEOs, committing to the continued safety and well-being of vaccinated individuals as the top priority in the development of the first COVID-19 vaccines."	• Laundry list of alleged omissions do not render false (Mov. 21, 22-25 & n.22; Reply 8 & n.10) • Inactionable as too generalized (Mov. 21 & n.19; Reply 8-9)
11/5/20	74	Conf. call	The efforts against the COVID-19 pandemic include advancing the vaccine candidate and more importantly initiating Phase III trials for our long-acting antibody combination, ***which is incredibly promising***.	• Challenge abandoned as undisputedly unrelated to AZD1222 (Mov. n.23; Reply n.7)
11/5/20	75	Conf. call	We continue to lead across multiple fronts in the global response to the COVID-19 pandemic. ***Progress has been made with our vaccine, AZD1222***	• Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 7) • Inactionable puffery and opinion (Mov. 18-19, 25-26 & nn.16, 24; Reply 7) • Safe harbor for FLS (Mov. 26-27; Reply 9-10)
11/5/20	76	Conf. call	. . . Andy Pollard has just presented a few weeks ago, you may have missed it, at an infection conference actually data from (inaudible) showed that ***the immune response in the 56 to 69 year olds and 69 and 70 and above looks very similar to the response of the 18 to 55 year olds. In that regard, we're feeling good about the immunogenicity in all the age groups that we're testing***. And we think we will have data from those age groups for the readout.	• Alleged omissions regarding "manufacturing error," protocol amendment, and "sufficiency" of 55+ participants do not render false (Mov. 18-19, 20, 22-24; Reply 4-6) • Challenge ignores express disclosures regarding limited number of participants 55+ and testing "at various doses" (Mov. 18, 22, 24; Reply 3-4 & n.4) • Inactionable critique of trial design (Mov. 17, 18, 22-24 & nn.15, 22; Reply 6) • Inactionable challenge to clinical data interpretation (Mov. 19-20 & n.17; Reply 4, 7) • Inactionable opinion (Mov. 20; Reply 7-8) • Ongoing analysis of incoming data is protected by safe harbor for FLS (Mov. 26-27; Reply 9-10)